

## REMARKS

Favorable reconsideration and allowance of this application are requested.

Pending claims 1-6, 8, 11, 12, 19, 22, 24-26, 28-29, 32-34 and 36-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. U.S. Patent 6,344,209 in view of Bell et al. U.S. Patent Pub. 2002/0055143 A1. Reconsideration is requested.

### 1. Response to Art-Based Rejections

Pending claim 1 states:

A composition for the controlled release of an antineoplastic agent and an immunostimulant comprising an antineoplastic agent and an immunostimulant dispersed throughout a matrix wherein said composition is the hydration reaction product of an aqueous mixture comprised of:

- an inorganic compound capable of undergoing hydration and/or crystallization,
- an antineoplastic agent,
- an immunostimulant, and
- at least one of: a matrix polymer, a complexing agent, and a conditioning agent.

Saito relates to an apatite-coated solid composition. Preformed apatite particles and a medicinal are simply mixed with a polyester. It does not relate to a composition where the active agents are "dispersed throughout **a matrix**" and which is "**the hydration reaction product of an aqueous mixture comprised of: an inorganic compound capable of undergoing hydration and/or crystallization**, an antineoplastic agent, **an immunostimulant**, and at least one of: a matrix polymer, a complexing agent, and a conditioning agent (emphasis added)."

Bell relates to a bone precursor composition comprising a calcium cement which is suitable for injection, wherein said calcium cement includes monobasic calcium phosphate monohydrate and beta-tricalcium phosphate.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made (35 USC §103(a)) to incorporate the immunostimulants (GM-CSF) of Bell within the coated solid compositions of Saito. However as noted above, the "coated solid composition" of Saito is very different from the matrix composition of the subject invention and combining Saito and Bell would in no way arrive at the composition of the subject invention. There is no suggestion in these references of including both an antineoplastic agent (e.g. cisplatin) and an immunostimulant (e.g. GM-CSF).

Claims 1-6, 8, 11, 12, 19, 22, 24-26, 28-29, 32-34 and 36-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al in view of Saito et al. U.S. Patent 6,344,209 and further in view of Bell et al. U.S. Patent Pub. 2002/0055143 A1. Reconsideration is requested.

Petersen relates to a bone graft substitute composition consisting of calcium sulfate, a mixing solution and a plasticizing substance.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the antitumor/antineoplastic agents (cisplatin) of Saito or the immunostimulants of (GM-CSF) of Bell within the bone substitute compositions of Petersen. However as noted above, the "coated solid composition" of Saito is very different from the matrix composition of the subject invention and combining Saito and Bell would in no way arrive at the composition of the subject invention. Again, there is no suggestion in these references of including both an antineoplastic agent (e.g. cisplatin) and an immunostimulant (e.g. GM-CSF).

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## 2. Response to Double Patenting Rejection

None of the commonly owned patents cited by the Examiner as the basis of the double patenting rejection relate to a sustained release matrix composition containing BOTH an antineoplastic agent and an immunostimulant. It is this combination that provides an enhanced immune response to cancer cells. Accordingly, the presently claimed invention is not a mere obvious variant to the inventions defined in the cited patents forming the basis of the Examiner's double patenting rejection. Withdrawal of the double patenting rejection is therefore in order as the presently claimed invention is patentably distinct thereover.

## 3. Fee Authorization

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By:           /Bryan H. Davidson/            
Bryan H. Davidson  
Reg. No. 30,251

BHD:dlb  
901 North Glebe Road, 11<sup>th</sup> Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100